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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,492	10/13/2006	Andreas Meinke	SONN:078US/10509902	3198

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,492	MEINKE ET AL.	
	Examiner	Art Unit	
	PADMA v. BASKAR	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38,41,43 and 46-60* is/are pending in the application.

4a) Of the above claim(s) *51-52 and 55-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,40-43,46-50,53 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on 2/4/08 is acknowledged.

Status of claims

2. Claims 1-37 , 39, 44-45 are cancelled.

Claims 38 and 41, 43 and 46-60 are pending.

Claims 38, 40, 41, 42-43, 46-47, 49, 53 and 54 have been amended.

Claims 38, 40-43, 46-50 and 53-54 are under examination.

Claims 51-52 and 55-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions M.P.E.P § 821.03.

Claim Rejections - 35 USC 101 withdrawn

3. In view of amendment to claim 38, the rejection made under 35 U.S.C. 101 as set forth in the previous office action is withdrawn.

Claim Rejections - 35 USC 112, first paragraph withdrawn

4. In view of applicants arguments of record, the written description rejection of claims 38, 40-43, 46-50, 53 and 54 under 35 U.5.C. 112, first paragraph is withdrawn.

Claim objections/ Rejections - 35 USC § 112 moot

5. In view of cancelation claim 39, the rejection under 35 U.S.C. 112, second paragraph is moot.

Claim Objection withdrawn

6. In view of amendment to the claim 38 in reciting elected sequence ,SEQ.ID.NO 32 , the objection made in the previous Office action is withdrawn.

Claim Rejections - 35 USC 112, first paragraph maintained

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

8. The scope of rejection of claims 38, 40-43, 46-50, 53 and 54 under 35 U.S.C. 112, first paragraph, is maintained for the same reasons as set forth in the previous office action.

Please note "hyperimmune serum reactive antigen comprising an amino acid sequence from any of SEQ.ID.NO:32 or antigenic fragments " "an amino acid sequence of: amino acids 6-28, 54-59, 135-147, 193-205, 274-279, 284-291,298-308, 342-347, 360-366, 380-386, 408-425, 437-446, 457-464, 467-477, 504-510, 517-530, 535-543, 547-553, 562-569, 573-579, 592-600, 602-613, 626-631, 638-668 and/or 396-449 of SEQ ID NO: 32" embraces fragments of fragments and thus are viewed as variants.

Applicant argues that the structure of SEQ.ID.NO:32 and said sequence is identified by antibodies to *S.epidermidis*. Further fragments of said sequence were disclosed in Table 1and these fragments are expected to have structural attributes including antigenic index regions etc. Therefore, the examiner's allegations that the specification fails to disclose critical residues is misplaced.

Applicant arguments are fully considered but found to be non persuasive because the claim does not recite that SEQ.ID.NO:32 is an *S.epidermidis hyperimmune serum reactive antigen. Further, Table 1 recites the fragments consisting of* 6-28, 54-59, 135-147, 193-205, 274-279, 284-291,298-308, 342-347, 360-366, 380-386, 408-425, 437-446, 457-464, 467-477, 504-510, 517-530, 535-543, 547-553, 562-569, 573-579, 592-600, 602-613, 626-631, 638-668 and/or 396-449 of SEQ ID NO: 32 and reactive with *S.epidermidis hyperimmune serum.* Therefore, the claim language as recited in the claims read on variants (see the explanation above) and hence examiners interpretation that the specification fails to disclose critical residues is appropriate.

Applicant argues that making antigenic fragments have been taught in the specification pages 13-14 and 32 and enablement does not require that every species of generic class has to be shown in the working examples and enablement is not precluded by the necessity for some experimentation such as routine screening. *In re Wands* 858 F.2d 731,737 (Fed. Cir. 1988).

Applicant arguments are fully considered but found to be non persuasive because

enablement requires making and using the claimed invention and specification fails to teach how to use the broadly claimed variants . The requirement of 35 USC 112 first paragraph are drawn to teaching of how to make and use the claimed invention and are not drawn to screening of molecules in order to determine whether or not the invention would function as claimed. However, the screening assays suggested by applicant do not enable the claimed invention because the court found in *Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004 that screening assays are not sufficient to enable an invention since they are merely a wish or plan for obtaining the claimed chemical invention. Therefore, one would not know how to use the broadly claimed variants . Therefore, it is appropriate to maintain the rejection.

Claim Rejections - 35 USC 102 maintained

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. The rejection of claims 38, 40-43, 46-49 and 53-54 under 35 U.S.C. 102(b) as being anticipated by Kimmerly WJ , AAG81977 , WO200134809-A2 is maintained as set forth in the previous Office action.

Applicant argues that Kimmerly does not anticipate the current claims because Kimmerly does not provide enabling disclosure of the pharmaceutical composition. Further , applicant states that the art teaches genomic sequence and not a translated protein.

Applicant arguments are fully considered but found to be non persuasive because the art provides the protein and the structure of the sequence. Applicant did not provide any supporting evidence that it is a non enabling disclosure. The art also discloses that the protein is obtained from *S.epidermidis* SR1 strain which is useful as a vaccine composition since the protein contains anti-bacterial activity.

11. The rejection of 38, 40-43, 46-49 and 53-54 under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al Patent No. 6380370. is maintained as set forth in the previous Office action.

Applicant argues that Doucette-Stamm et al do not anticipate the current claims because Kimmerly does not provide enabling disclosure of the pharmaceutical composition. Further , applicant states that the art teaches genomic sequence and not a translated protein.

Applicant arguments are fully considered but found to be non persuasive because the art provides the protein and the structure of the sequence. Applicant did not provide any supporting evidence that it is a non enabling disclosure. The art also discloses that the protein is obtained from *S.epidermidis* which is useful as a vaccine composition since the protein is immunogenic as the antigen is reactive to serum antibodies (see column 40). Therefore , the rejection is maintained.

Conclusion

12. Claims 38, 40-43, 46-50, 53 and 54 are rejected.

This application contains claims 51-52 and 55-60 drawn to an invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

14. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile

must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shannon Foley can be reached on (571) 272-0898

Respectfully,
/Padma v Baskar/
Examiner, Art Unit 1645

/Shanon A. Foley/

Supervisory Patent Examiner, Art Unit 1645